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To:  
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Docket System  
Status Report  
Docket Book

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**PCT**

NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing  
(day/month/year)

01 FEB 2006

Applicant's or agent's file reference

RCK-0017

International application No.

PCT/US04/37925

International filing date (day/month/year)

12 November 2004 (12.11.2004)

Priority date (day/month/year)

24 November 2003 (24.11.2003)

Applicant

THE ROCKEFELLER UNIVERSITY

**IMPORTANT NOTIFICATION**

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

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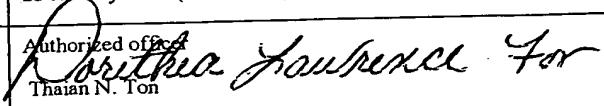
Form PCT/IPEA/416 (July 1992)

## PATENT COOPERATION TREATY

**PCT**

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

## (PCT Article 36 and Rule 70)

Applicant's or agent's file reference  RCK-0017 International application No. PCT/US04/37925		FOR FURTHER ACTION  See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)  International filing date (day/month/year) 12 November 2004 (12.11.2004)	Priority date (day/month/year) 24 November 2003 (24.11.2003)
International Patent Classification (IPC) or national classification and IPC  IPC(8): C12N 5/00, 5/02, 15/00, 15/09, 15/63, 15/70, 15/74, 15/85, 15/87; A01K 67/00, 67/03, 67/027 and US Cl.: 435/325, 320.1, 455, 463; 800/13, 14			
Applicant  THE ROCKEFELLER UNIVERSITY			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>  </u> sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>			
Date of submission of the demand  28 July 2005 (28.07.2005)		Date of completion of this report  23 January 2006 (23.01.2006)	
Name and mailing address of the IPEA/US  Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer  Thaian N. Ton Telephone No. (571) 272.1600	

Form PCT/IPEA/409 (cover sheet)(July 1998)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US04/37925

**I. Basis of the report**1. With regard to the elements of the international application:<sup>\*</sup>

- the international application as originally filed.
- the description:  
pages 1-71, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- the claims:  
pages 72-75, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- the drawings:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
 the language of publication of the international application (under Rule 48.3(b)).  
 the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing

- contained in the international application in printed form.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority in written form.  
 furnished subsequently to this Authority in computer readable form.  
 The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
 The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4.  The amendments have resulted in the cancellation of:

- the description, pages NONE  
 the claims, Nos. NONE  
 the drawings, sheets/fig NONE

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).<sup>\*\*</sup>

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US04/37925**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)

Claims NONE  YES  
Claims 1-20  NO

Inventive Step (IS)

Claims NONE  YES  
Claims 1-20  NO

Industrial Applicability (IA)

Claims 1-20  YES  
Claims NONE  NO**2. CITATIONS AND EXPLANATIONS**

Please See Continuation Sheet

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/37925

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V. 2. Citations and Explanations:

Claims 1-20 the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 1-6 lack novelty under PCT Article 33(2) as being anticipated by Trempus *et al.* The claims are directed to methods for isolating a self-renewing, multipotent cell by obtaining a cell from a sample and sorting the cells based upon the presence of CD34 and the amount of a selected slow-cycling cell marker expressed by the cell. The claims are also directed to cells isolated by the claimed method. Trempus teach the isolation of epithelial cells with stem and progenitor cell characteristics using a CD34 specific antibody, and identifying in that population a subset of cells also expression alpha-6 integrin. See Abstract. Particularly, they teach that keratinocytes were isolated from the dorsal skin of mice, cells were separated by flow cytometry and the resulting cells isolated. See Materials and Methods, pp. 502-503. Thus, Trempus teach the claimed invention because they teach a progenitor cell isolated by the presence of both CD34 and another marker expressed by the cell.

Claims 7, 9-16 lack novelty under PCT Article 33(2) as being anticipated by Yuan *et al.*, or Roy *et al.*, or Fujikawa *et al.* or Coffin *et al.* Note that claims 9-16 are directed to cell populations, produced by a particular method. The method by which the cells are produced fails to differentiate the cells from the art, thus, art that teaches the products teaches the claims.

Yuan teach the generation of a transgenic mouse expressing EGFP under the CNP promoter. They observe the expression of EGFP, and isolated oligodendrocyte progenitor cells from the mice using fluorescence activated cell-sorting (FACS). See Methods and Materials, p. 530-531.

Roy teach the identification isolation of oligodendrocyte progenitor cells from adult human subcortical white matter. Particularly, they teach the dissociation and culture of cells from adult human brain (p. 9987, Materials and Methods, 2<sup>nd</sup> column), the transfection of these cells with a transgene encoding the CNP2 promoter with targeted GFP expression. They teach that the cells expressing GFP were then sorted using flow cytometry and a FACS machine. See p. 9989, 1<sup>st</sup> column.

Fujikawa teach the purification of isolated hepatic progenitor cells using GFP-transgenic mice, and isolating cells from the mice. Particularly, they teach that GFP-transgenic mice, which express GFP under the cytomegalovirus enhancer-beta-actin promoter. Liver tissues were isolated from the mice, and then the cells were sorted and characterized. The cells were then sorted by FACS and analyzed. See pp. 163-164. Fujikawa teach that the cells that were sorted had immature characteristics (p. 166, 2<sup>nd</sup> column) and that the cells showed *in vitro* differentiation potential to produce hepatocytes. See p. 167, #3.5.

Coffin teach the generation of populations of transduced human primary cells by FACS sorting using GFP expression.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/37925

## Supplemental Box

Particularly, they teach that human hematopoietic stem cells were transduced using a HSV1 vector expressing GFP. See Abstract. The transduced cells were then sorted to remove GFP-negative cells.

Claims 7, 8-16 lack novelty under PCT Article 33(2) as being anticipated by Bartz *et al.* Bartz teach the isolation of immature dendritic cells from Langerhans cells by sorting using two markers, CD34+ or CD133+ (see p. 139, #2.3) and then cells from this population were further sorted and isolated using CLA expression (p. 139, #2.4). The resulting cells were the isolated and cultured and then analyzed (p. 139, #2.5).

Claims 17-18 lack novelty under PCT Article 33(2) as being anticipated by Punzel *et al.* Punzel teach the culture and expansion of human hematopoietic stem cells, by growing the cells on fibroblast feeder cells using LTBMC medium. See p. 93, 2<sup>nd</sup> column. Note that the LTBMC medium that they teach contains IMDM, which contains calcium chloride (.219 g/L). Thus, they anticipate the claims.

Claims 19-20 lack novelty under PCT Article 33(2) as being anticipated by Krestel *et al.* Krestel teach the generation of transgenic mice using a transgene encoding humanized GFP that is regulated by doxycycline. Expression was activated when the transcription factor tTA (tet-dependent transactivator) was expressed by the transgene. See Abstract and Materials and Methods.